Wroclaw, 1.02.2021

Assessment of Er:YAG (yttrium-aluminium-garnet) Laser-Assisted Surgical Treatment in Medication-Related Osteonecrosis of the Jaw (MRONJ): A Clinical Trial

Study Protocol

1. Examination and qualification of patients
2. Taking X-ray and performing CBCT.
3. Initiation of antibiotic therapy: amoxicillin with clavulanic acid (875 mg + 125 mg) every 12 hours. In patients allergic to penicillin, clindamycin (600 mg every 12 hours). The antibiotic must be taken 3 days before the procedure and continued 14 days after the treatment.
4. Scheduling follow-up visits 1 and 2 weeks post-procedure and at 3 and 6 months. Assessment of the condition of the surrounding mucosa, wound healing, complications and overall treatment effectiveness.
5. Anesthesia of patients using anesthesia without vasoconstrictor additives (Mepivacaine 3%, Scandodenst, Septodont). Creating access with a 15C scalpel and detaching tissues using a raspator with a semicircular tip (15 mm in diameter).

   Procedure:

   a. Study group: Tissue debriding until hard, healthy, lively bleeding bone is exposed using Er:YAG laser with parameters: 400mJ, 6W, 15Hz, 5/8 water cooling, laser tip with a diameter of 800 microns.
   b. Control group: Tissue debriding until hard, healthy, lively bleeding bone is exposed using rose-shaped rotary drills (8 mm diameter) with water cooling at a speed not exceeding 40.000 rpm.

   Closing wounds with 5/0 non-resorbable sutures and taking them off after 2 weeks.

Statistical analysis

1. Characterizing the study sample in terms of variables included in the study.
2. Highlighting treatment effectiveness indicators.
3. Performing logistic regression analysis.
4. Using the Student's t-test for intergroup differences.